Remarks

Upon entry of the amendment, claims 1-2, 11-16, 19-20, 22, and 24-55 will be pending. Claims 3-10, 17-18, 21 and 23 have been canceled herein. Applicants reserve the right to pursue the canceled subject matter in a divisional application. New claims 24-55 have been added. Support for the newly added claims is found throughout the specification as filed. Specifically, support for new claims 24-55 may be found at, for example, Table 1 at page 75, row 4, as indicated as "Gene No. 3;" Table 2 at page 82 at row 3 for "clone HKAOV90"; page 96, line 29 to page 98, line 16; page 98, lines 22-27; page 99, lines 8-13; page 99, line 26 to page 103, line 12; page 103, line 19 to page 106, line 21; page 107, line 26 to page 109, line 10; page 109, lines 1-10; page 112, lne 27 to page 114, line 32; page 146, line 24 to page 151, line 6; page 155, line 27 to page 157, line 21; page 174, lines 10-18; page 177, line 20 to page 179, line 19; page 266, lines 14-21; page 266, lines 25-27; page 267, lines 1-20; Example 8 at page 301; Example 9 at page 303; Example 10 at page 305; Example 11 at page 306; Example 22 at page 327. Thus, no new matter has been introduced.

Applicants request that the Examiner take note of Reference C listed on the IDS, wherein said reference teaches on page 8591 that the present invention (now known in the art as Prominin-2) is found in adenocarcinoma and kidney tissue, as the specification teaches on page 14.

The Restriction Requirement

On page 2 of Paper No. 6, the Examiner has restricted the claimed invention into ten (10) Inventions. The Examiner contends that the inventions are distinct, each from the other, and thus, has required an election under 35 U.S.C. § 121.

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, Group II, encompassing claims 11-12 and 16 and by newly added claims 24 to 55, drawn to a purified polypeptide of SEQ ID NO:48 and clone ID HKAOV90, for further prosecution.

Applicants respectfully submit that the Examiner failed to consider whether the claimed invention was "independent" as required by the plain and unambiguous meaning of the applicable statute, 35 U.S.C. §121; and even if the claimed inventions represent "distinct" inventions, Applicants submit that to search and examine the subject matter of all the Inventions together would not be a serious burden on the Examiner.

The Examiner cited 35 U.S.C. §121 as authority in requiring restriction of claims 1-23. Applicants contend that the Examiner improperly exercised his discretion in requiring restriction of the claimed invention because said action is inconsistent with the plain and unambiguous meaning of 35 U.S.C. §121, which states in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." The term "independent" is not equivalent to the term "distinct" per the MPEP §802.01 at 800-3. The Examiner has not shown that the claimed inventions are "independent" as required. Therefore, Applicants respectfully submit that finality of the restriction cannot be imposed until reconsideration of this matter.

Secondly, Applicants submit that even where two patentably distinct inventions appear in a single application, restriction remains improper *unless* it can be shown that the search and examination of both inventions would entail a "serious burden" (*See* M.P.E.P. § 803). In the present situation, no such showing has been made.

Even assuming, *arguendo,* that Inventions I-X represent distinct inventions, Applicants submit that to search and examine the subject matter of all the Inventions together would not be a serious burden on the Examiner. Applicants submit that a search of polynucleotide claims of the invention would provide useful information for examining claims directed to both polynucleotides and the polypeptides encoded by these polynucleotides. In certain claims this is especially true because the polynucleotide sequence of these claims is defined in part by the polypeptide that the polynucleotide sequence encodes. Further, Applicants point out that, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence of the encoded polypeptide. For example, see Reference C listed on the IDS, wherein both the polypeptide sequence and polynucleotide GenBank accession number is given.

Moreover, the Examiner included in Invention I methods of making a polypeptide (see Paper No. 20031030, page 2). A search for this invention would absolutely provide information for Invention II, polypeptides. Thus the restriction between these two inventions should be withdrawn.

Similarly, a search of the polypeptide claims of the invention would clearly provide useful information for the examination of claims directed to antibodies either produced in

response to or having affinity for the subject polypeptides. This is because antibodies are frequently defined by the antigens that they are produced in response to and the epitopes to which they bind. Moreover, in many publications where an antibody is described, the antigen that it was produced in response to is also described.

Further, searches of publications directed to polynucleotides and the use of those polynucleotides would clearly be overlapping. This is so because in many, if not most, publications which describe polynucleotides, these molecules are described by their function, characterization and/or expression profile. Thus, a search of polynucleotide claims would also provide the Examiner with art directed to the manner in which the claimed polynucleotides could be used in diagnostic and therapeutic indications.

Further, searches of publications directed to polypeptides and the use of those polypeptides would clearly be overlapping. This is so because in many, if not most, publications which describe polypeptides, these molecules are described by their function. Thus, a search of polypeptide claims would also provide the Examiner with art directed to the manner in which the claimed polypeptides could be used to treat disease states.

In view of the above, Applicants submit that the searches for polynucleotides, polypeptides, and antibodies; as well as methods of diagnosing, preventing and treating disease states using the nucleic acids and proteins of the subject invention; and methods of identifying a binding partner to a polypeptide of the subject invention; and methods of identifying an activity in a biological assay of the subject invention; and the translational products produced by the methods of identifying an activity in a biological assay wherein said translational products have said activity would clearly be overlapping. Accordingly, Applicants request that, in view of M.P.E.P. § 803, the claims of all of Inventions I to X should be searched and examined in the subject application.

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn and the instant claims be examined in one application. However, should the restriction be maintained, Applicants request rejoinder of the claims of Group II with claims 14-15 of Group I (process of making polypeptides) once the claims of Group II are found allowable. In light of the decisions in *In re Ochiai,* 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer,* 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the

treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

> in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if claims of Group II are found allowable, Applicants respectfully request that the claims 14-15 of Group I be rejoined and examined for patentability.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144 should it be made final.

Conclusion

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: December 8, 2003

Respectfully submitted,

By _____

Janet M. Martineau
Registration No.: 46,903
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 315-2723

JMM/KN/ba